[Submitting Counsel on Signature Page]

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN FRANCISCO DIVISION

In re LIDODERM ANTITRUST LITIGATION	Master File No. 14-md-02521-WHO MDL No. 2521
THIS DOCUMENT RELATES TO: ALL ACTIONS	**PLAINTIFFS' MOTION TO EXCLUDE IN PART EXPERT TESTIMONY OF MR. HARSHA MURTHY** **ORAL ARGUMENT REQUESTED** Date: September 15, 2017 Time: 9:00 a.m. Courtroom: 2, 17th Floor The Honorable William H. Orrick

FILED UNDER SEAL

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NOTICE OF MOTION AND *DAUBERT* MOTION

TO THE PARTIES AND THEIR ATTORNEYS OF RECORD:

PLEASE TAKE NOTICE that on September 15, 2017, at 9:00 a.m., before the Honorable William H. Orrick, Plaintiffs will and hereby do move the Court for an order excluding parts of the expert testimony of Harsha Murthy. In his report, purportedly based on "the record," Mr. Murthy opines that **"**it is ***very unlikely*** that a company in Watson's position would have launched a generic version of Endo's Lidoderm® patch 'at-risk.'" Murthy Report ¶13(a) (emphasis in original).[1] A witness who is testifying based on his experience must tether that experience to "sufficient facts or data" and "reliably appl[y] the principles and methods to the facts of the case." Fed. R. Evid. 702. Mr. Murthy made no effort to examine the facts in this case specifically or in the generic drug industry generally to determine what a reasonable company would do here, rendering his opinion wholly speculative and thus unreliable. Failing to meet the standards set forth in Federal Rule of Evidence 702 and *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579 (1993), Mr. Murthy's opinion on this issue should be excluded.

Accordingly, Plaintiffs ask the court to strike paragraphs 13(a), 23-28, 37-50 and 52-57 of Mr. Murthy's Report, and preclude all testimony related to those paragraphs.

This motion is based upon this Notice of Motion and Motion; the incorporated Memorandum of Points and Authorities; the concurrently filed Declaration of Renae D. Steiner ("Steiner Decl.") and exhibits thereto; the pleadings and other filings in this action; Plaintiffs' anticipated Reply in support of this Motion; and any argument Plaintiffs may present to the Court.

[1] Per this Court's ruling (ECF No. 746; Hr'g Tr. of June 6, 2017, at 4:8, 4:17-19, 5:14-21), the "in Watson's position" portion was to be removed or an at-issue waiver would be implied. Defendants have not done so to date.

MEMORANDUM OF POINTS AND AUTHORITIES

I. INTRODUCTION

Harsha Murthy has been offered by Defendants as an expert on pharmaceutical company decision-making relating to "at-risk" and authorized generic ("AG") launches. Mr. Murthy offers four opinions in his report; Plaintiffs move to exclude one opinion in particular. The opinion Plaintiffs move to strike is summarized in Murthy Report ¶13(a) (Steiner Decl. Ex. 1), where Mr. Murthy claims that:

> A generic company will consider many factors when evaluating whether to launch a product 'at risk,' including without limitations:
>
> (i) the likelihood and timing of obtaining all regulatory approvals;
>
> (ii) the likelihood of an adverse litigation outcome (including potential damages based on the magnitude of sales of the branded product—which could be trebled—and how an adverse ruling could affect "first to file" opportunities);
>
> (iii) the company's manufacturing capabilities and ability to meet demand; and
>
> (iv) the likelihood and timing of entry of additional generic manufacturers.
>
> When evaluating the record relating to these factors, it is my opinion that it is ***very unlikely*** that a company in Watson's position would have launched a generic version of Endo's Lidoderm patch 'at risk.'

Id. (formatting supplied).[2]

As detailed below, Mr. Murthy's opinion should be excluded because, while he purports to "evaluat[e] the record relating to these factors," he does not cite any Watson documents or testimony or any industry data related to these factors to support his speculation that a company "in Watson's position" was very unlikely to launch a generic Lidoderm patch at risk. (Perhaps this is because the Watson documents and testimony belie his unsupported opinion.) His opinion, untethered to any data or factual examination, is not a reliable basis for his conclusion that a reasonable generic company would evaluate those factors and "would be ***very unlikely*** to launch at-risk." *Id.* Therefore, Mr.

[2] Mr. Murthy repeats these factors and begins his analysis of them beginning at Murthy Report ¶ 23.

Murthy's opinion related to whether a reasonable generic company would have launched generic Lidoderm at-risk should be struck under (1) Fed. R. Evid. 702(b), as it is not based on sufficient – or any -- facts or data, and (2) Fed. R. Evid. 702(c) and (d), which require that expert testimony be the product of reliable principles and methods, and that the testimony be tethered "to the facts of the case."

II. ARGUMENT

A. Legal Standard.

Although an expert witness can be qualified as an expert based on his experience, a witness who is testifying based on his experience must relate that experience to "sufficient facts or data" and "reliably appl[y] the principles and methods to the facts of the case." Fed. R. Evid. 702. As this court held in *Fujifilm*, "[u]nder the reliability requirement, the expert testimony must 'ha[ve] a reliable basis in the knowledge and experience of the relevant discipline.'" *Fujifilm Corp. v. Motorola Mobility LLC*, No. 12-CV-03587-WHO, 2015 WL 1737951, at *1 (N.D. Cal. Apr. 8, 2015) ("*Fujifilm*") (quoting *Primiano v. Cook*, 598 F.3d 558, 565 (9th Cir. 2010)). More than "subjective belief or unsupported speculation" is required to surmount a *Daubert* challenge. *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 599 (1993). "[T]he word 'knowledge' connotes more than subjective belief or unsupported speculation." *Samuels v. Holland Am. Line–USA Inc.*, 656 F.3d 948, 952 (9th Cir. 2011) ("*Holland Am. Line*") (quoting *Daubert*, 509 U.S. at 590).

The district court's "duty to act as gatekeeper and to assure the reliability of proffered expert testimony before admitting it applies to all (not just scientific) expert testimony." *United States v. Hermanek*, 289 F.3d 1076, 1093 (9th Cir. 2002) (citing *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 147 (1999)). "The burden is on the proponent of the expert testimony to show, by a preponderance of the evidence, that the admissibility requirements are satisfied." *Fujifilm*, 2015 WL 1737951, at *2 (citing *Lust By & Through Lust v. Merrell Dow Pharm., Inc.*, 89 F.3d 594, 598 (9th Cir. 1996) and Fed. R. Evid. 702 advisory committee's note). "If evidence lacks either reliability or relevance, it must be excluded." *Cooper v. Brown*, 510 F.3d 870, 943 (9th Cir. 2007).

B. Mr. Murthy does not describe how his opinion, unmoored to any facts or data, is sufficient on the likelihood of a reasonable generic company launching at-risk.

Mr. Murthy hurdles from his list of factors that he believes a generic pharmaceutical company would consider to his speculative opinion that a reasonable company would not launch generic Lidoderm at-risk by *ipse dixit*: after listing a factor he believes a reasonable generic company would consider, Mr. Murthy dispenses with the need for any analysis, facts or data, and merely concludes that the presence of these factors would make at-risk launch "very unlikely." But, bare assertions of belief are not reliable expert testimony: "If the witness is relying solely or primarily on experience, then the witness must explain *how* that experience leads to the conclusion reached, *why* that experience is a sufficient basis for the opinion, and *how* that experience is reliably applied to the facts." Fed. R. Evid. 702 advisory committee's note to 2000 amendment (citation omitted) (emphasis added).

1. Mr. Murthy does not rely on any facts or data and does not apply any facts or data to form a reliable basis for his opinions.

Mr. Murthy purportedly uses his experience to identify factors he believes a reasonable company would consider in deciding whether to launch generic Lidoderm at risk. In coming to his conclusions, Mr. Murthy addresses exactly zero facts or data relevant to his factors. Mr. Murthy does not "evaluate the record" nor does he supply facts or data from industry reports or from his own experience—he cites no documents related to the first factor, one unrelated citation as to the second factor, and does not even address the fourth factor. On the third factor—the company's manufacturing capacity and ability—he notes simply that *at the time of the settlement* (May 2012), Watson did not have launch quantities, but he cites no evidence to support his actual opinion—that because Watson did not have launch quantities of generic Lidoderm in May 2012, a reasonable company would not have launched at-risk between August 2012 and September 2013.

An opinion that is neither scientific nor technical but is sufficiently specialized can be admitted under Rule 702 if it is "sufficiently supported by factual information." *Fujifilm,* 2015 WL 1737951, at *2-3. The difference between the testimony found to be admissible in *Fujifilm* and Mr. Murthy's testimony is stark. In *FujiFilm*, Mr. Pardy, a marketing executive with 25 years of experience in marketing mobile technology, including at Nokia and BlackBerry, offered the opinion that "that there

was a 'deliberate strategy' by smartphone manufacturers to 'converge' on the standalone digital camera market." 2015 WL 1737951, at *3. The opposing party moved to exclude that opinion, arguing that Mr. Pardy "cites no empirical data" to support it. *Id*. The party tendering the expert countered that Mr. Pardy was a "seasoned marketing veteran who thoroughly reviewed smartphone market data, industry reports, [and] contemporaneous accounts of consumer behavior and preferences" in reaching his conclusions. *Id*. This court denied the motion to exclude, noting that the testimony was sufficiently specialized and supported by factual information:

> While the opinion is neither scientific nor technical, it is sufficiently specialized to merit admission under Rule 702. ***It is also sufficiently supported by factual information.*** The various materials that Pardy identifies in support of his opinion distinguish this case from *Samuels v. Holland Am. Line–USA Inc.*, 656 F.3d 948 (9th Cir. 2011), on which Motorola relies, Mot. 7. In that case, the Ninth Circuit affirmed the exclusion of expert testimony "to the effect that entering the water [at a particular beach] is extremely dangerous and that this danger is commonly known throughout the cruise line industry." 656 F.3d at 952. The court explained that one of the experts "was unable to provide any materials from the cruise line industry to support [his opinion]," and that the expert's research consisted of "little more than a quick internet search regarding [the beach] and a few telephone calls." *Id*. at 952–53. The other expert had never worked for a cruise line and "failed to specify in her declaration what information she relied on in reaching her conclusions." *Id.* at 953***. Here, in contrast, Pardy has specifically identified various materials in support his opinion and has worked for the smartphone industry.*** *See, e.g.*, Pardy Rpt. ¶¶ 25–44.

Id. (emphasis added).

Here, although Mr. Murthy purports to opine as to what a hypothetical reasonable company in Watson's position would do, he does not cite any factual information supporting his opinion. In particular, as detailed further below, he cites no evidence *regarding Watson* that support any of the factors that he claims a reasonable company in Watson's position would consider. This omission of any relevant facts relating to Watson, sufficient by itself to warrant exclusion of his opinion, is rendered even more unreliable because Mr. Murthy acknowledges that "Not all generic companies look at their launches the same way. It is very much a function of the strategy, the decision-making process, the individuals, what is their place in the market. Just as there are different people with different outlooks

on life, there are different companies. Generic companies have different views about how they look at at-risk launches." Steiner Decl. Ex. 2 (Murthy Tr. at 242:8-22).

Since every generic company is admittedly different, Mr. Murthy would necessarily need to rely on facts or data regarding Watson to reliably opine on what he purports to opine on – the likelihood that a reasonable company in Watson's position would launch generic Lidoderm at risk. As an imperfect proxy for what a company in Watson's position would have done, Mr. Murthy could have offered evidence or analysis of what other companies have done in what he would consider to be similar scenarios. But, he does not do that, either. Unlike the *Fujifilm* expert, and like the proffered experts in *Holland Am. Line*, Mr. Murthy's opinion here is based on nothing but his own beliefs or speculation, as explained below.

(a) Factor 1: "the likelihood and timing of securing all regulatory approvals" (¶23(i))

Mr. Murthy did not cite to any Watson documents or interview any Watson witnesses about the actual ***likelihood and timing of obtaining regulatory approvals***, did not cite to facts or data (such as industry studies) on the likelihood and timing of ANDA approvals or Citizen Petition decisions for companies in like situations and did not cite to any personal experience related to the likelihood or timing of obtaining approval of an ANDA or obtaining a decision on a Citizen Petition.[3] Ex. 1 (Murthy Report at ¶¶23-28). He testified that he did not know of the strength of, Defendants' views on, or industry views on either the ANDA or the Citizen Petition. Ex. 2 (Murthy Tr. at 289:21-23) ("All I know is, as of this date in April 2012, they had not gotten an ANDA approval from the FDA") and 286:21-24 ("The only thing I know is that, as of the dates I was looking at, the citizens petition, there had not been a decision.").[4]

[3] At his deposition, Mr. Murthy admitted that he "was not asked to specifically go back and look at Watson's history on getting ANDA approvals . . . I am generally aware that many of the major players you have mentioned this afternoon, Ms. Steiner, like Teva, like Mylan, like Watson, have very good records of getting ANDA approvals." Ex. 2 (Murthy Tr. at 236:12-21 and 237:4-14).

[4] Mr. Murthy was not aware of the relevant factual record in this case. For example, in Report ¶25, he opined that it would be unreasonable for a company (like Watson) to make a decision to launch in advance of regulatory approvals. When asked whether he was aware of an internal Watson communication reflecting that FDA had communicated to Watson that its "TA packet is now complete"

Another reason to strike Mr. Murthy's opinion is that there is no fit between his purported factor considered, his discussion of the factor and his ultimate conclusions. For example, the first factor he claims to consider is "the likelihood and timing of securing necessary regulatory approvals." Yet, his opinion does not address either the likelihood that Watson (or any reasonable generic company) would have received regulatory approval, nor does he opine on what the timing for those regulatory approvals would be, other than to state that, "It is my experience that there is no certainty that either a federal court or the FDA (or both) will render decisions on these matters by a date certain." *Id*. at ¶26. He then opines that "a reasonable executive in Watson's position would not have not made any decision on whether to launch generic Lidoderm 'at risk' at the time Watson entered the settlement, for the simple reason that significant regulatory matters, namely the FDA approval of Watson's ANDA and the disposition of the Citizen's Petition, remained outstanding as of such date." *Id*. at ¶28. Mr. Murthy's conclusion that a reasonable executive would not have made a decision until regulatory approvals were secured is unrelated to his actual factor: the likelihood and timing of regulatory approvals.

(b) Factor 2: "the likelihood of an adverse litigation outcome (including the potential damages based on the magnitude of sales of the branded product and how the adverse ruling could affect "first to file" opportunities)" (¶23(ii))

Mr. Murthy did not cite to any Watson documents, witness testimony, or interviews of any Watson witnesses about the actual ***likelihood of an adverse litigation outcome***, and he did not cite to any facts or data (such as statistical studies or the opinions of patent experts) on the likelihood of an

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and tentative approval was forthcoming, and of Watson's reaction that "this is great news . . . . We are locked and ready to go," Murthy testified he had never seen this information. Ex. 2 (Murthy Tr. at 273:20-23) (referring to Ex. 1243, Steiner Decl. Ex 3). Indeed, it is not clear that Mr. Murthy even understands what Tentative Approval ("TA") means: "Well, tentative approval can mean any number of things. . . . but even a tentative approval doesn't mean you're going to get the final decision in your favor." Ex. 2 (Murthy Tr. at 273:13-19). Tentative Approval is defined in regulations as a notification from the FDA that, while an unexpired patent or regulatory exclusivity currently precludes Final Approval, an ANDA otherwise meets the requirements for approval under the Federal Food, Drug, and Cosmetic Act. *See* 21 C.F.R. § 314.3(b).

adverse litigation outcome in cases like this one and did not even cite to any personal experience related to the likelihood of an adverse litigation outcome. Ex. 1 (Murthy Report at ¶¶37-50). The only citation contained within this section is to that of the report of Dr. Carlton, an economist, whom Mr. Murthy cites solely for the proposition that *if* a generic company is found to have marketed an infringing product, it *could be* liable for damages. *Id.* at ¶¶38, n. 22 and 48, n. 23 ("If Watson launched 'at risk' and was ultimately found to be willfully infringing, Watson could be liable for hundreds of millions of dollars in damages."). But, that citation does nothing to address Mr. Murthy's opinion that the "likelihood of any adverse litigation outcome" would "weigh heavily against a decision to launch generic Lidoderm at risk." *Id*. at ¶46. Murthy testified that he made no effort to actually assess the likelihood of an adverse patent litigation result for Watson. Ex. 2 (Murthy Tr. at 305:11-306:2) ("I did not do an independent examination of the patent litigation or the claims in the patent suit. . . . I merely looked at the fact that the litigation was unresolved, that is, not a final, unappealable appellate order, and that there would have been large risks to Watson if they launched at risk with this one factor, with the litigation still being outstanding.").

Here, Mr. Murthy did not draw on any facts or data—whether from personal experience, the case record or industry analysis—to support his opinion. He did not study the actual conduct of any companies (including Watson) when it came to at-risk launch scenarios, including for blockbuster drugs like Lidoderm, and did not seek out any industry data. Ex. 2 (Murthy Tr. at 203:22-207:6; 204:7-21 and 207:11-18).

(c) <u>Factor 3: "the company's manufacturing capabilities and ability to meet demand for the generic product" (¶23 (iii))</u>

When discussing ***manufacturing capability or ability*** to meet demand for launch quantities of generic Lidoderm during the at-risk launch period, Mr. Murthy does not address manufacturing capability or ability during the at-risk launch time period (*i.e.*, August 23, 2012 through September 2013).[5] *See* Ex. 1 (Murthy Report ¶¶52-57). Rather, his citations are to testimony that Watson did not

[5] Defendants have argued that, had the patent litigation continued, an appellate decision would have been reached in their estimation, at the end of September 2013. *See, e.g.*, Steiner Decl. Ex. 4 (Bell Report at ¶109(c)) ("Third, Endo would not have launched its AG any earlier than October 1, 2013, as

have launch quantities *at the time of settlement* (May 2012), and would not launch without the ability to supply the entire generic demand. *Id.* at ¶55, n. 26 and ¶56, n. 30. He does not explain how Watson's lack of launch quantities months *before* the date Plaintiffs contend Watson would have launched reliably informs his conclusion that "Watson's lack of finished inventory and inability to supply the entire generic market with generic Lidoderm [would] weigh heavily against a decision to launch generic Lidoderm 'at risk'" in the period before the appellate court would have resolved any patent appeal. *Id*. at ¶57.

(d) Factor 4: "the likelihood and timing of entry of additional generic competitors" (¶ 23(iv))

Mr. Murthy never addresses his fourth factor *at all*: after conclusorily mentioning in paragraphs 13 and 23 that the ***likelihood and timing of entry of additional generic manufacturers*** would be a factor to consider, he then neglects to ever mention it again in the body of his report.

2. Mr. Murthy's testimony, based solely on his speculative beliefs, is unreliable.

Absent grounding an opinion to factual or other support, the Ninth Circuit has declined to admit such testimony. Experience must provide a knowledge base that goes beyond "subjective belief or unsupported speculation." *Holland Am. Line*, 656 F.3d at 952 (excluding proffered experts offering opinions that the surf on the ocean side of Cabo San Lucas is extremely dangerous and commonly known throughout the cruise-line industry, when neither witness cited to materials from cruise lines or interviewed cruise line employees, but rather relied solely on experience) (citing *Daubert*, 509 U.S. at 590); *Sterling Sav. Bank v. Poulsen*, No. C-12-01454 EDL, 2013 WL 3945989, at *8 (N.D. Cal. July 29, 2013) (expert qualified to address the California banking industry in general terms, but not qualified to opine on whether failing to inquire about the mental capacity of elders before executing financial documents was financial elder abuse, because expert relied only on "some materials on elder abuse, including training materials for banks regarding elder abuse and articles about financial elder abuse"); and *Lucido v. Nestle Purina Petcare Co.*, 217 F. Supp. 3d 1098, 1102-03 (N.D. Cal. 2016)

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the appeal would still have been pending."). For purposes of this motion only, Plaintiffs accept October 1, 2013 as the date that the patent appeal would have been decided.

(veterinarian's 15 years of experience sufficient to testify about what her clients indicated to her about the importance of safety in pet food, but because she had not offered a reliable basis to opine, she was precluded from testifying "what a reasonable consumer considers material when deciding whether to purchase dog food").

Accordingly, Mr. Murthy's opinion concerning at-risk launch by a reasonable company in Defendant Watson's position, based entirely on his subjective belief and unsupported speculation, should be excluded.

III. CONCLUSION

For the reasons set forth above, pursuant to Federal Rule of Evidence 702, Plaintiffs respectfully request that the Court grant Plaintiffs' motion and exclude the opinion and related testimony Mr. Murthy's Report (¶¶13(a), 23-28, 37-50 and 52-57) concerning whether a reasonable company would launch at-risk.

Dated: June 30, 2017

Respectfully submitted,

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ATTESTATION

I, Renae D. Steiner, am the ECF User whose identification and password are being used to file this Plaintiffs' Motion to Exclude in Part Expert Testimony of Mr. Harsha Murthy . I attest under penalty of perjury that concurrence in this filing has been obtained from all counsel.

DATED: June 30, 2017

/s/ *Renae D. Steiner*
Renae D. Steiner

CERTIFICATE OF SERVICE

I hereby certify that on June 30, 2017, I electronically filed the foregoing document using the CM/ECF system, which will send notification of such filing to all counsel of record registered in the CM/ECF system. I also caused a copy of the foregoing document to be served via email on counsel of record for all parties.

/s/ *Renae D. Steiner*
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